ClearPoint DIAGNOSTIC LABORATORIES

At the ConVergence Center | 2501 South State Highway 121 Business | Suite 1200
Lewisville, TX 75067-8188 |Phone: 972.966.7700 | Fax: 972.966.7799
www.clearpointlabs.com

LAB ALERT – NEW TEST

NOTIFICATION DATE: 11/5/2013
EFFECTIVE DATE: 11/19/2013

BK Viral Load By PCR

TEST CODE: BKVQNT

INTERFACE CODE: 1004208

TEST CODES / INTERFACE CODES TO DEACTIVATE: BKVQT/1000120
BKVNB/1000113
BKVMOL/1002475

METHODOLOGY: Qiagen ASR Quantitative Real-Time PCR

CLINICAL UTILITY: BKV primary infection occurs in infancy and has a seroprevalance of over 80% in adolescents with no clinical symptoms in immunocompetent hosts. However, reactivation of the latent virus in the urogenital tract results in interstitial nephritis and BKV-associated nephropathy (BKVAN) in recipients of kidney transplants (5-10%) and hemorrhagic cystitis in patients with hematologic malignancies. Prospective viral load monitoring of BKV DNA in plasma and urine are useful to exclude a diagnosis of BKVAN and to monitor the course of BKV infection. In 2005, an international consensus panel proposed a plasma or serum titer of >10,000 copies/mL to be high positive predictor of BKVAN with a specificity of 93%. Urine specimens may have very high viral loads and may overlap between symptomatic and asymptomatic patients. Consequently, urinary viral load of more than 10^7 copies/mL has been proposed to be a significant risk factor for BKVAN. Furthermore, trending of viral DNA post-transplant for significant increases may be helpful in predicting the early onset of BKVAN. A viral load increase of less than one log may not be clinically significant. A definite diagnosis of BKVAN requires demonstration of BKV inclusions in tubular and glomerular epithelial cells in renal allograft biopsy specimens.

Please note that there are no changes in the specimen collection, transport and storage conditions of the specimens. This change DOES NOT affect the sharing of specimens for other tests.

ClearPoint DIAGNOSTIC LABORATORIES

At the ConVergence Center | 2501 South State Highway 121 Business | Suite 1200
Lewisville, TX 75067-8188 |Phone: 972.966.7700 | Fax: 972.966.7799
www.clearpointlabs.com

PERFORMED:	Monday-Wednesday-Friday
COLLECTION:	5 mL (Min. 2 mL) of Peripheral Blood in Lavender top EDTA tube; 1 mL CSF (Min. 0.5 mL) or 5mL Urine (Min. 2 mL) in a sterile plastic screw capped container or tube. Do not centrifuge any specimen type.
STABILITY (FROM COLLECTION TO INITIATION OF TESTING):	Blood: Ambient: 8 hours; Refrigerated: 5 days, Frozen: Unacceptable CSF and Urine: Ambient: 8 hours; Refrigerated: 5 days; Frozen: 1 month
TRANSPORT:	Refrigerated
REFERENCE RANGE:	Target Not Detected (TND)
REPORTABLE RANGE:	250 to 10,000,000 copies/mL ($\log_{10}$ 2.40 to $\log_{10}$ 7.00 copies/mL)
RESULTS REPORTED:	1-4 days
CPT CODE:	87499
PERFORMING LAB:	med fusion
GENERAL INFORMATION:	The analytical measurement range of the new test is 250 to 10,000,000 copies/mL ($\log_{10}$ 2.40 to $\log_{10}$ 7.00 copies/mL). The range of the current BK quantitative assay is 250 to 100,000,000 copies/mL. Our data on extensive analytical verification shows a good linear correlation between the current assay and the new assay. However, please note that: • The results of the new and old test may NOT be directly comparable. This is especially true at a very low and very high viral load which is expected to have maximum variance. • The results will be reported in copies/mL and $\log_{10}$ copies/mL on the new assay. The log values more closely represent the biological and laboratory processes since each iteration of a RT-PCR process has a multiplicative effect.

ClearPoint DIAGNOSTIC LABORATORIES

At the ConVergence Center | 2501 South State Highway 121 Business | Suite 1200
Lewisville, TX 75067-8188 |Phone: 972.966.7700 | Fax: 972.966.7799
www.clearpointlabs.com

In order to provide the best quality care to our patients who are being monitored using the current BK viral load assay, we will offer testing by both the new and the old assay for a period of 6 weeks after implementation. A positive BK viral load result (Plasma and Urine only) on the new assay will be reflexed to be tested by the old laboratory developed assay at no charge upon physician request (positives will be batched and tested once a week). This will allow physicians to re-baseline the viral load if necessary. The parallel testing will only be performed the first time the patient is tested on the new assay. No additional specimen collection required for the reflex testing. If you require parallel testing, please call the lab at 972-966-7167.

ORDERING:

The new BK viral RT-PCR load assay will replace our current laboratory developed BKV assay. The following codes will be deactivated effective 11/19/2013:

TESTS TO BE DEACTIVATED		
Test Code	**Test Name**	**Interface Code**
BKVQT	BK Virus QNT PCR Blood	1000120
BKVNB	BK Virus QNT PCR Non-Blood	1000113
BKVMOL	BK Virus QNT PCR	1002475

Please contact the Technical Director of Molecular Laboratory, Dr. Neelam Dhiman, at 972-966-7359 with any questions or concerns that you may have regarding new BK viral load testing.

ORDER / CONTACT INFORMATION: *ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799*